

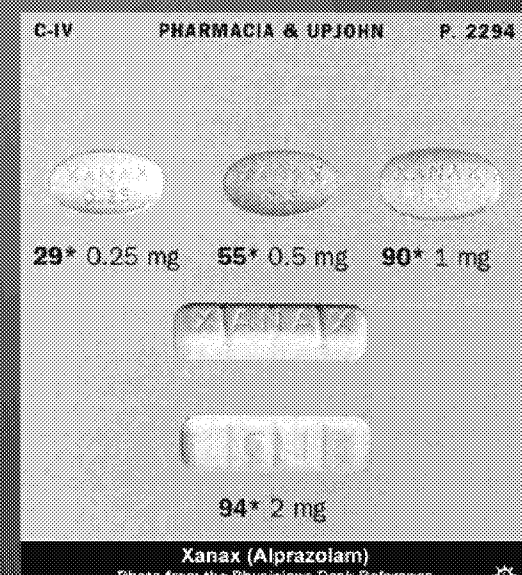
Alprazolam Xanax[®] (Z-bars)

C-IV

- Drug abusers often prefer alprazolam due to its rapid onset and longer duration of action
- Alprazolam was ranked third in the number of prescriptions for controlled substances in 2003, 2004, 2005 and 2006*
- For all sales of generic pharmaceuticals, alprazolam was ranked 7th**

* Source IMS Health

** Source Verispan VONA





Stimulants

Amphetamine Salts C-II

- Adderall C-II

Methylphenidate C-II

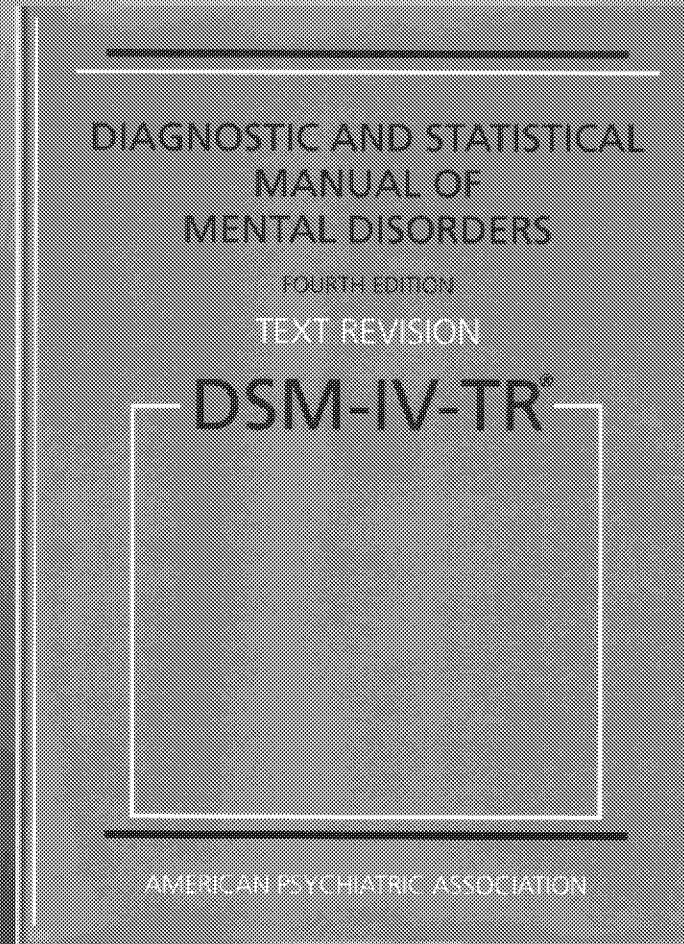
- Ritalin®
- Concerta®



Ritalin® / Concerta® / Adderall

- Used legitimately to treat ADHD
- Used non-medically to get high and as an academic “performance-enhancer” to improve memory and improve concentration – gain the edge
 - Higher GPA
 - Higher SAT / ACT score
 - Get that scholarship

REQUIRED READING



Attention-Deficit and Disruptive Behavior Disorders

Attention-Deficit/Hyperactivity Disorder

Diagnostic Features

Some hyperactive-impulsive or inattentive symptoms that cause impairment must have been present before age 7 years, although many individuals are diagnosed after the symptoms have been present for a number of years, especially in the case of individuals with the Predominantly Inattentive Type (Criterion B)

A1c). There may be frequent shifts from one uncompleted activity to another. Individuals diagnosed with this disorder may begin a task, move on to another, then turn to yet something else, prior to completing any one task. They often do not follow through on requests or instructions and fail to complete schoolwork, chores, or other duties (Criterion A1d). Failure to complete tasks should be considered in making this diagnosis only if it is due to inattention as opposed to other possible reasons (e.g., failure to understand instructions, defiance). These individuals often have difficulties organizing tasks and activities (Criterion A1e). Tasks that require sustained mental effort are experienced as unpleasant and markedly aversive. As a result, these individuals typically avoid or have a strong dislike for activities that demand sustained self-application and mental effort or that require organizational demands or close concentration (e.g., homework or paperwork) (Criterion A1f). This avoidance must be due to the person's difficulties with attention and not due to a primary oppositional attitude, although secondary oppositionalism may also occur. Work habits are often disorganized and the materials necessary for doing the task are often scattered, lost, or carelessly handled and damaged (Criterion A1g). Individuals with this disorder

- Fails to give close attention to details...make careless mistakes in schoolwork, work
- Difficulty sustaining attention in tasks
- Does not seem to listen when spoken to
- Does not follow through on instructions
- Difficulty organizing tasks
- Often loses things necessary for tasks
- Easily distracted
- Forgetful

- (h) is often easily distracted by extraneous stimuli
- (i) is often forgetful in daily activities

- (2) six (or more) of the following symptoms of **hyperactivity-impulsivity** have persisted for at least 6 months to a degree that is maladaptive and inconsistent with developmental level:

Hyperactivity

- (a) often fidgets with hands or feet or squirms in seat
- (b) often leaves seat in classroom or in other situations in which remaining

- Fidgets
- Can't remain seated
- Restlessness
- Difficulty awaiting turn
- Often interrupts or intrudes

- B. Some hyperactive-impulsive or inattentive symptoms that caused impairment were present before age 7 years.
- C. Some impairment from the symptoms is present in two or more settings (e.g., at school [or work] and at home).

that require and poor understanding, typical of self and others as well as behavior. Family members are especially likely to believe parent-child

with successful treatment. On average, individuals with Attention-Deficit/Hyperactivity Disorder obtain less schooling than their peers and have poorer vocational achievement. Also, on average, intellectual level, as assessed by individual IQ tests, is several points lower in children with this disorder compared with peers. At the same time, great variability in IQ is evidenced: individuals with Attention-Deficit/Hyperactivity Disorder may show intellectual development in the above-average or gifted range. In its severe form, the disorder is markedly impairing, affecting social, familial, and scholastic adjustment. All three subtypes are associated with significant impairment. Academic deficits and school-related problems tend to be most pronounced in the types marked by inattention (Predominantly Inattentive and Combined Types), whereas peer rejection and, to a lesser extent, accidental injury are most salient in the types marked by hyperactivity and impulsivity (Predominantly Hyperactive-Impulsive and Combined Types). Individuals with the Predominantly Inattentive Type tend to be socially passive and appear to be neglected, rather than rejected, by peers.

A substantial proportion (approximately half) of clinic-referred children with Attention-Deficit/Hyperactivity Disorder also have Oppositional Defiant Disorder or Conduct Disorder. The rates of co-occurrence of Attention-Deficit/Hyperactivity Disorder with these other Disruptive Behavior Disorders are higher than with other mental disorders, and this co-occurrence is most likely in the two subtypes marked by hyperactivity-impulsivity (Hyperactive-Impulsive and Combined Types). Other associated disorders include Mood Disorders, Anxiety Disorders, Learning Disorders, and Communication Disorders in children with Attention-Deficit/Hyperactivity Disorder. Although Attention-Deficit/Hyperactivity Disorder appears in at least 50% of clinic-referred individuals with Tourette's Disorder, most individuals with Attention-Deficit/Hyperactivity Disorder do not have accompanying Tourette's Disorder. When the two disorders coexist, the onset of the Attention-Deficit/Hyperactivity Disorder often precedes the onset of the Tourette's Disorder.

There may be a history of child abuse or neglect, multiple foster placements, neurotoxin exposure (e.g., lead poisoning), infections (e.g., encephalitis), drug exposure in utero, or Mental Retardation. Although low birth weight may sometimes be associated with Attention-Deficit/Hyperactivity Disorder, most children with low birth weight do not develop Attention-Deficit/Hyperactivity Disorder, and most children with Attention-Deficit/Hyperactivity Disorder do not have a history of low birth weight.

Associated laboratory findings. There are no laboratory tests, neurological assessments, or attentional assessments that have been established as diagnostic in the clinical

There are no laboratory tests, neurological assessments, or attentional assessments that have been established as diagnostic in the clinical assessment of Attention-Deficit/Hyperactivity Disorder

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There are no specific physical features associated with Attention-Deficit/Hyperactivity Disorder, although minor physical anomalies (e.g., hypertelorism, highly arched palate, low-set ears) may occur at a higher rate than in the general population. There may also be a higher rate of accidental physical injury.

Specific Culture, Age, and Gender Features

Attention-Deficit/Hyperactivity Disorder is known to occur in various cultures, with variations in reported prevalence among Western countries probably arising more from different diagnostic practices than from differences in clinical presentation.

It is difficult to establish this diagnosis in children younger than age 4 or 5 years, because their characteristic behavior is much more variable than that of older children and may include features that are similar to symptoms of Attention-Deficit/Hyperactivity Disorder. Furthermore, symptoms of inattention in toddlers or preschool children are often not readily observed because young children typically experience few demands for sustained attention. However, even the attention of toddlers can be held in a variety of situations (e.g., the average 2- or 3-year-old child can typically sit with an adult looking through picture books). Young children with Attention-Deficit/Hyperactivity Disorder move excessively and typically are difficult to contain. Inquiring about a wide variety of behaviors in a young child may be helpful in ensuring that a full clinical picture has been obtained. Substantial impairment has been demonstrated in preschool-age children with Attention-Deficit/Hyperactivity Disorder. In school-age children, symptoms of inattention affect classroom work and academic performance. Impulsive symptoms may also lead to the breaking of familial, interpersonal, and educational rules. Symptoms of Attention-Deficit/Hyperactivity Disorder are typically at their most prominent during the elementary grades. As children mature, symptoms usually become less conspicuous. By late childhood and early adolescence, signs of excessive gross motor activity (e.g., excessive running and climbing, not remaining seated) are less common, and hyperactivity symptoms may be confined to fidgetiness or an inner feeling of jitteriness or restlessness. In adulthood, restlessness may lead to difficulty in participating in sedentary activities and to avoiding pastimes or occupations that provide limited opportunity for spontaneous movement (e.g., desk jobs). Social dysfunction in adults appears to be especially likely in those who had additional concurrent diagnoses in childhood. Caution should be exercised in making the diagnosis of Attention-Deficit/Hyperactivity Disorder in adults solely on the basis of the adult's recall of being inattentive or hyperactive as a child, because the validity of such retrospective data is often problematic. Although supporting information may not always be available, corroborating information from other informants (including prior school records) is helpful for improving the accuracy of the diagnosis.

Lisdexamfetamine (Vyvanse®)

- Lisdexamfetamine is a new chemical entity consisting of d-amphetamine (schedule II) covalently bound to the amino acid, L-lysine.
- Lisdexamfetamine per se is pharmacologically inactive.
- Upon oral ingestion, the lysine moiety is cleaved in the gastrointestinal system releasing d-amphetamine. Thus, lisdexamfetamine is a “pro-drug” for d-amphetamine.
- Pharmacology and abuse potential of lisdexamfetamine are similar to d-amphetamine.

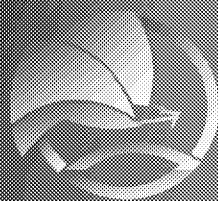


Methods of Diversion

- Practitioners / Pharmacists
 - Illegal distribution
 - Self abuse
 - Trading drugs for sex
- Employee pilferage
 - Hospitals
 - Practitioners' offices
 - Nursing homes
 - Retail pharmacies
 - Manufacturing / distribution facilities
- Pharmacy / Other Theft
 - Armed robbery
 - Burglary (Night Break-ins)
 - In Transit Loss (Hijacking)
 - Smurfing
- Patients / Drug Seekers
 - Drug rings
 - Doctor-shopping
 - Forged / fraudulent / altered prescriptions
- The medicine cabinet / obituaries
- The Internet
- Pain Clinics

Where are the Pharmaceuticals Coming From?

- Friends and Family for Free
- Medicine Cabinet
- Doctor Shopping
- Internet
- Pain Clinics



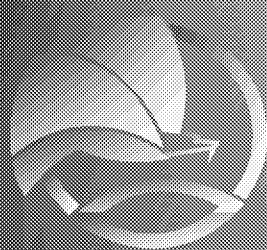
Prescription Fraud

- **Fake prescriptions**

- Highly organized
- Use real physician name and DEA Registrant Number
 - Contact Information false or “fake office”
 - (change locations often to avoid detection)
- Prescription printing services utilized
 - Not required to ask questions or verify information printed

- **Stolen prescriptions**

- Forged
- “Smurfed” to a large number of different pharmacies



Doctor Shopping



Prescription Drug Monitoring Programs

Map of the United States showing the status of Prescription Drug Monitoring Programs (PDMPs) by state as of February 2010. The map uses three shades of gray to indicate the status: dark gray for 'Operational PDMPs', medium gray for 'Enacted PDMP legislation, program not yet operational', and white for 'Legislation pending'. Missouri (MO) is white, indicating legislation is pending. Most other states are dark gray, indicating operational PDMPs. A legend in the bottom right corner explains the shading. State abbreviations are labeled on the map, and a list of states with pending legislation (VT, ME, NH, MA, RI, CT, NJ, DE, MD, DC) is shown on the right with lines pointing to their locations.

Research is current as of June 13, 2012



Diversion via the Internet

Domestic 'Rx' Flow

1. Consumer in Montana orders hydrocodone on the Internet

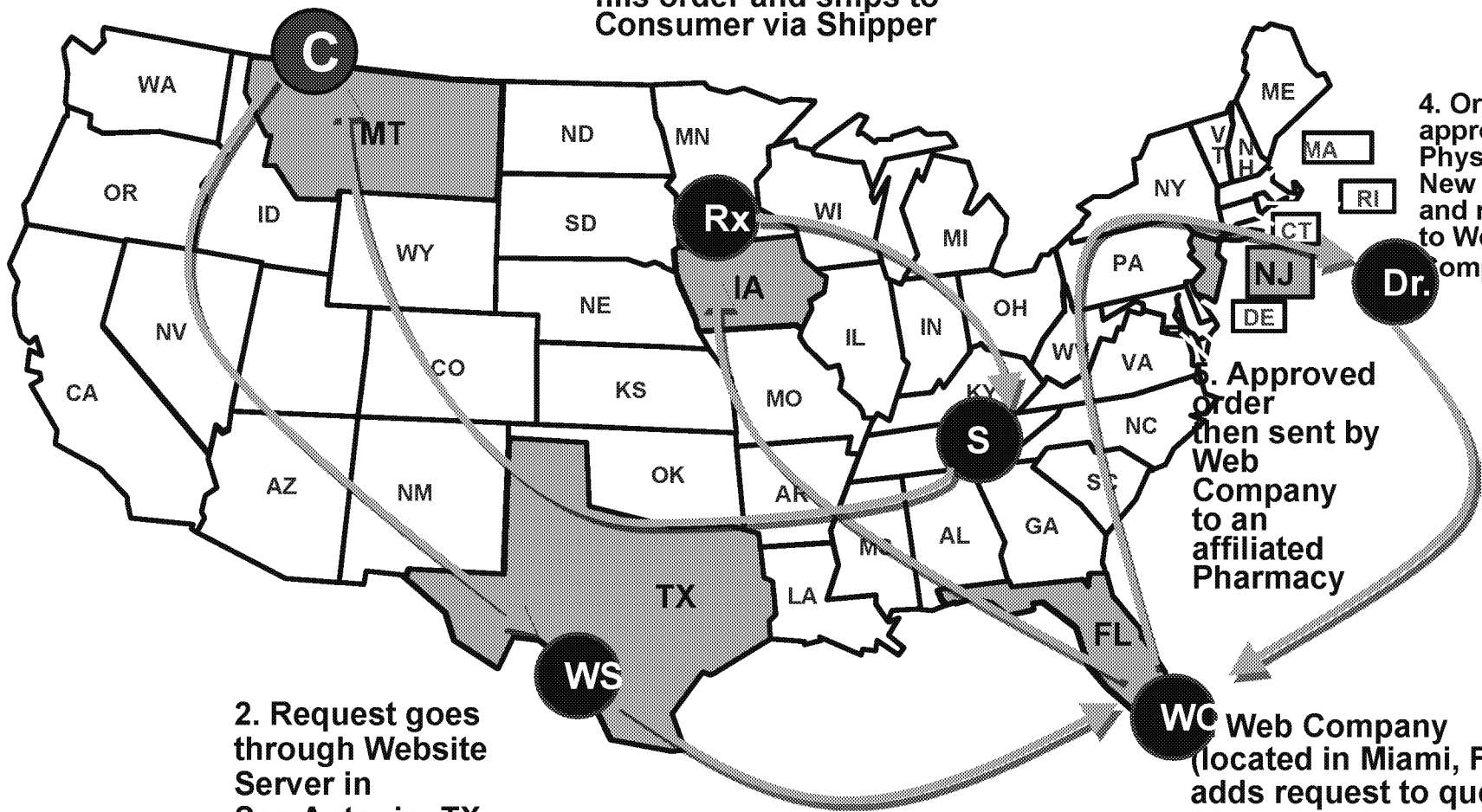
6. Pharmacy in Iowa fills order and ships to Consumer via Shipper

4. Order is approved by Physician in New Jersey and returned to Web company

5. Approved order then sent by Web Company to an affiliated Pharmacy

3. Web Company (located in Miami, FL) adds request to queue for Physician approval

2. Request goes through Website Server in San Antonio, TX



Purchases of hydrocodone by Known and Suspected

Rogue Internet Pharmacies

January 1, 2006 – December 31, 2006

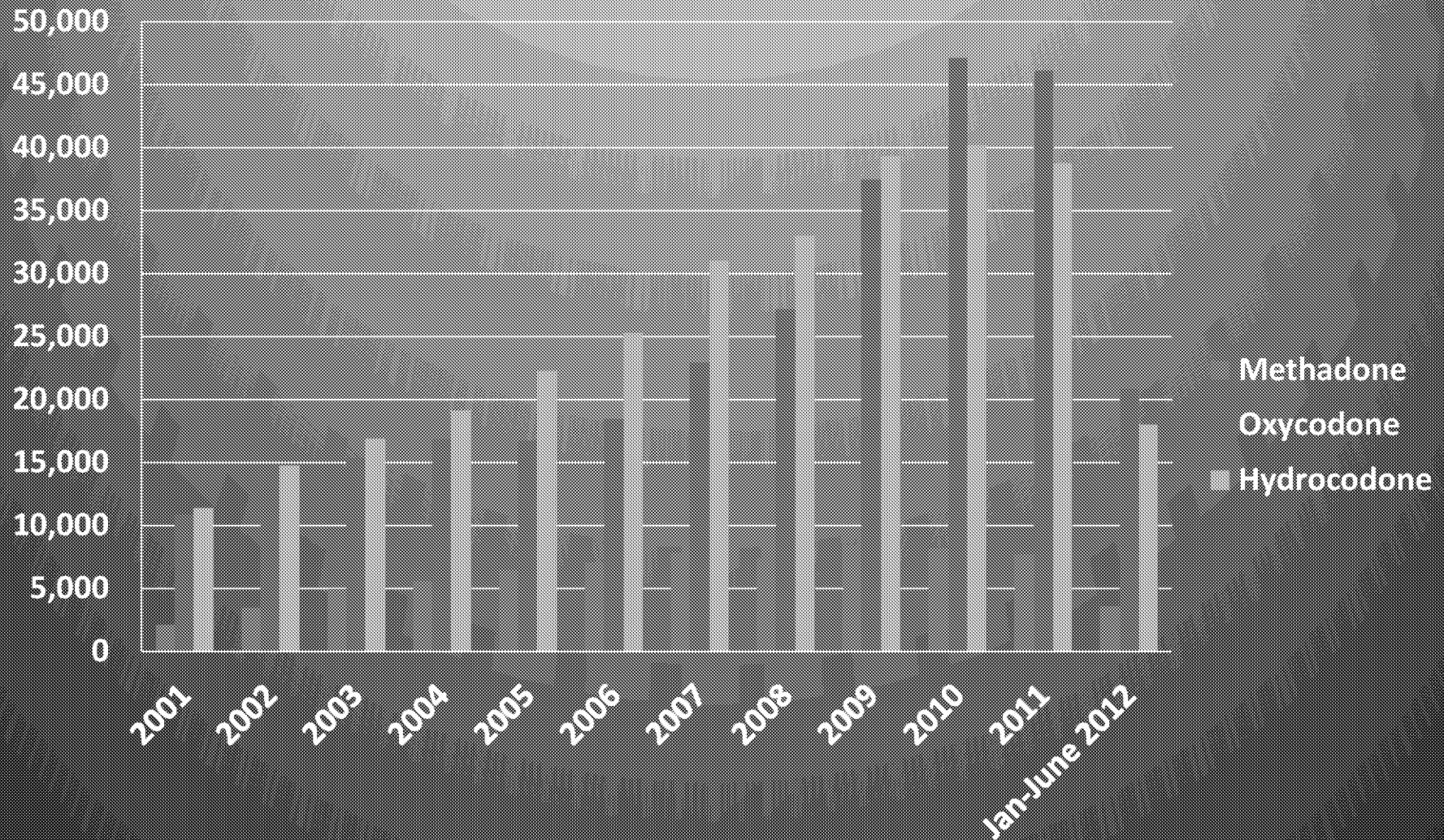
| | | | | | | |
|----|--|----------------|-----------------|----------------|-------|------------|
| 1 | | Hillsborough | TAMPA | FLORIDA | 33614 | 15,596,380 |
| 2 | | Pinellas | CLEARWATER | FLORIDA | 33765 | 9,077,816 |
| 3 | | Hillsborough | TAMPA | FLORIDA | 33614 | 8,760,876 |
| 4 | | Baltimore City | BALTIMORE | MARYLAND | 21213 | 5,876,300 |
| 5 | | Hillsborough | TAMPA | FLORIDA | 33619 | 5,718,200 |
| 6 | | Jefferson | RIVER RIDGE | LOUISIANA | 70123 | 4,892,900 |
| 7 | | Hillsborough | TAMPA | FLORIDA | 33634 | 4,733,290 |
| 8 | | Polk | LAKELAND | FLORIDA | 33813 | 4,564,480 |
| 9 | | Hillsborough | TAMPA | FLORIDA | 33612 | 4,220,840 |
| 10 | | Pinellas | CLEARWATER | FLORIDA | 33759 | 3,819,320 |
| 11 | | Hillsborough | TAMPA | FLORIDA | 33610 | 3,044,160 |
| 12 | | | | FLORIDA | 33809 | 3,039,490 |
| 13 | | | | | 70123 | 2,750,000 |
| 14 | | | | | 34652 | 2,664,120 |
| 15 | | | | | 33613 | 1,902,900 |
| 16 | | | | FLORIDA | 33801 | 1,726,020 |
| 17 | | Hillsborough | TAMPA | FLORIDA | 33612 | 1,619,765 |
| 18 | | Hillsborough | TAMPA | FLORIDA | 33604 | 1,570,350 |
| 19 | | Pinellas | TARPON SPRINGS | FLORIDA | 34689 | 1,464,900 |
| 20 | | Lincoln | DENVER | NORTH CAROLINA | 28037 | 1,402,450 |
| 21 | | Hillsborough | TAMPA | FLORIDA | 33617 | 1,282,800 |
| 22 | | Hillsborough | TAMPA | FLORIDA | 33619 | 1,272,860 |
| 23 | | Polk | LAKELAND | FLORIDA | 33813 | 1,039,400 |
| 24 | | Pasco | WESLEY CHAPEL | FLORIDA | 33543 | 1,030,950 |
| 25 | | Iredell | MOORESVILLE | NORTH CAROLINA | 28117 | 902,500 |
| 26 | | Polk | LAKELAND | FLORIDA | 33815 | 867,800 |
| 27 | | Broward | HOLLYWOOD | FLORIDA | 33021 | 865,700 |
| 28 | | Los Angeles | ENCINO | CALIFORNIA | 91436 | 798,100 |
| 29 | | Hillsborough | TAMPA | FLORIDA | 33604 | 793,350 |
| 30 | | Pasco | NEW PORT RICHEY | FLORIDA | 34652 | 583,400 |
| 31 | | Ravalli | FLORENCE | MONTANA | 59833 | 362,000 |
| 32 | | Hillsborough | TAMPA | FLORIDA | 33619 | 162,000 |
| 33 | | Broward | DEERFIELD BEACH | FLORIDA | 33441 | 112,600 |
| 34 | | Hillsborough | TAMPA | FLORIDA | 33614 | 49,600 |
| | | | | | | 2,339,321 |

98,566,711

Date Prepared: 03/07/2007 Source: ARCOS

National Forensic Laboratory Information System (NFLIS)

State and Local Law Enforcement Cases



Yearly estimates are published in NFLIS Annual Report (2001-2011) and NFLIS 2012 Midyear Report 177

NFLIS Drug Cases

(State and Local)

| | 2001 | 2002 | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | Jan-June 2012 |
|--------------------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|------------------|
| Methadone | 2,145 | 3,508 | 4,986 | 5,594 | 6,409 | 7,053 | 7,778 | 7,500 | 8,459 | 8,173 | 7,658 | 3,613 |
| Oxycodone | 10,926 | 13,906 | 15,396 | 16,818 | 16,721 | 18,456 | 22,960 | 27,207 | 37,489 | 47,088 | 46,065 | 20,787 |
| Hydrocodone | 11,386 | 14,756 | 16,933 | 19,147 | 22,259 | 25,272 | 31,007 | 32,985 | 39,326 | 40,206 | 38,765 | 18,033 |
| Morphine | 1,725 | 2,180 | 2,687 | 2,801 | 3,171 | 3,637 | 4,337 | 4,757 | 5,986 | 5,986 | 6,931 | 3,696 |
| Codeine | 2,959 | 3,070 | 3,116 | 3,354 | 2,743 | 2,787 | 2,962 | 3,026 | 3,439 | 3,390 | 3,530 | 1,599 |
| Meperidine | 465 | 425 | 343 | 268 | 258 | 294 | 283 | 251 | 244 | 167 | 151 | 64 |

Yearly estimates published in NFLIS Annual Report (2001-2011) and NFLIS 2012 Midyear Report

NFLIS Data

Federal, State and Local Cases:

| | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | 2012* |
|---------------|--------|--------|--------|--------|--------|--------|--------|
| MEPERIDINE | 312 | 301 | 316 | 237 | 193 | 150 | 84 |
| OXYMORPHONE | 17 | 45 | 129 | 344 | 781 | 2,689 | 1,881 |
| CODEINE | 2,631 | 2,707 | 3,038 | 3,177 | 3,181 | 3,014 | 2,194 |
| HYDROMORPHONE | 1,333 | 1,570 | 1,680 | 2,024 | 2,355 | 2,675 | 2,969 |
| METHADONE | 6,640 | 7,262 | 7,485 | 7,922 | 7,645 | 7,059 | 4,890 |
| MORPHINE | 3,563 | 4,189 | 4,930 | 6,037 | 6,385 | 6,690 | 5,849 |
| HYDROCODONE | 24,984 | 30,637 | 33,731 | 38,082 | 39,381 | 36,512 | 25,926 |
| OXYCODONE | 17,927 | 22,425 | 28,756 | 38,330 | 48,197 | 46,296 | 33,196 |

Federal, State and Local Reports:

| | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | 2012* |
|---------------|--------|--------|--------|--------|--------|--------|--------|
| MEPERIDINE | 342 | 332 | 339 | 274 | 268 | 159 | 94 |
| OXYMORPHONE | 17 | 47 | 139 | 387 | 868 | 3,045 | 2,086 |
| CODEINE | 2,978 | 3,059 | 3,478 | 3,629 | 3,646 | 3,398 | 2,455 |
| HYDROMORPHONE | 1,426 | 1,687 | 1,827 | 2,234 | 2,609 | 2,990 | 3,272 |
| METHADONE | 7,124 | 7,899 | 8,400 | 8,783 | 8,481 | 7,737 | 5,351 |
| MORPHINE | 4,036 | 4,685 | 5,731 | 7,104 | 7,440 | 7,768 | 6,657 |
| HYDROCODONE | 27,927 | 34,449 | 38,422 | 44,074 | 45,625 | 42,751 | 29,944 |
| OXYCODONE | 21,155 | 26,478 | 34,652 | 46,575 | 60,223 | 57,668 | 40,973 |

179
*2012 data is still being submitted, queried on 1/22/2013

New Felony Offense Internet Trafficking 10/15/2008

- 21 USC 841(h)(1): It shall be unlawful for any person to knowingly or intentionally:
 - (A) deliver, distribute, or dispense a controlled substance by means of the Internet, except as authorized by this title; or
 - (B) aid or abet any violation in (A)

What has been the reaction???

Per Se Violations

Automatic Violation of the CSA if any of the following occurs:

- No in-person medical evaluation by prescribing practitioner
- Online pharmacy not properly registered with modified registration.
- Website fails to display required information

Prattickers Adapt

Switch to overseas sites outside of U.S.
regulatory authority

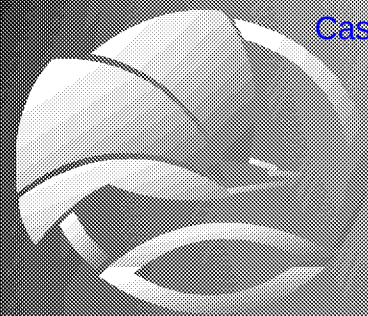
Non-controlled drugs

Current CSA Registrant Population

Total Population: 1,469,821

| | | |
|--------------------------|---|-----------|
| ➤ Practitioner | - | 1,148,956 |
| ➤ Mid-Level Practitioner | - | 222,773 |
| ➤ Pharmacy | - | 68,526 |
| ➤ Hospital/Clinic | - | 15,860 |
| ➤ Teaching Institution | - | 315 |
| ➤ Manufacturer | - | 544 |
| ➤ Distributor | - | 919 |
| ➤ Researcher | - | 9,642 |
| ➤ Analytical Labs | - | 1,511 |
| ➤ NTP | - | 1,310 |
| ➤ Importer/Exporter | - | 474 |
| ➤ ADS Machine | - | 404 |
| ➤ Chemicals | - | 1,056 |

2/08/2013



SOOOO...How many have
applied for registration for
Internet Pharmacy
Operations?????

39 applications filed

20 withdrawn

7 applications filed in error

2 pending

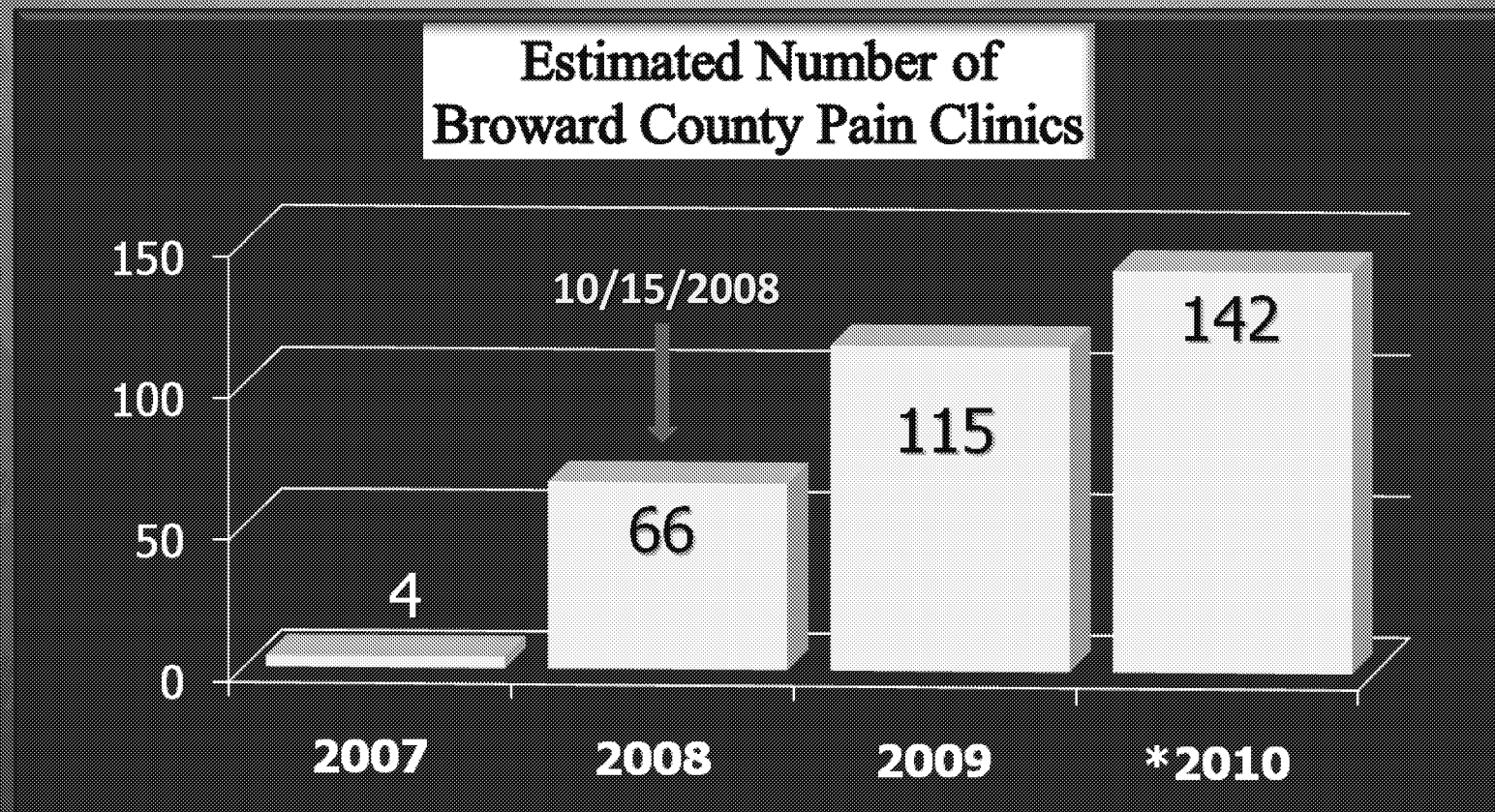
No applications approved thus far

*What took the place of Internet
Medical Care and Internet CS
pharmaceutical Distribution?*



Pain Clinics

Explosion of South Florida Pain Clinics



As of June 4, 2010, Florida has received 1,118 applications and has approved 1026

*As of May 14, 2010, Broward 142; Miami-Dade 79; Palm Beach 111

Explosion of South Florida Pain Clinics – All Providers (Current and Closed)

- All/State of Florida: 1,501
- Broward County: 236
- Miami-Dade County: 156
- Palm Beach County: 161
- Hillsborough County (Tampa area): 214


As of February 12, 2013.

Explosion of South Florida Pain Clinics – Currently Licensed Providers

- All/State of Florida: 390
- Broward County: 60
- Miami-Dade County: 46
- Palm Beach County: 32
- Hillsborough County (Tampa area): 63

As of February 12, 2013.

NFLIS – Federal, State, and local cases reported

| | Hydrocodone | Oxycodone |
|---|-------------|-----------|
| 2002 | 9,376 | 8,288 |
| 2003 | 12,130 | 9,715 |
| 2004 | 16,401 | 13,492 |
| 2005 | 21,190 | 14,643 |
| 2006 | 24,984 | 17,927 |
| 2007 | 30,637 | 22,425 |
| Ryan- Haight  | 2008 | 28,756 |
| | 2009 | 38,330 |
| | 2010 | 48,197 |
| | 2011 | 46,452 |
| | 2012 | 35,781* |

Medical Care ?

- Many of these clinics are prescription/dispensing mills.
- Minimal practitioner/patient interaction

Increased Law Enforcement Pressure

- Clinics migrating north and west
- Funded by owners in Florida

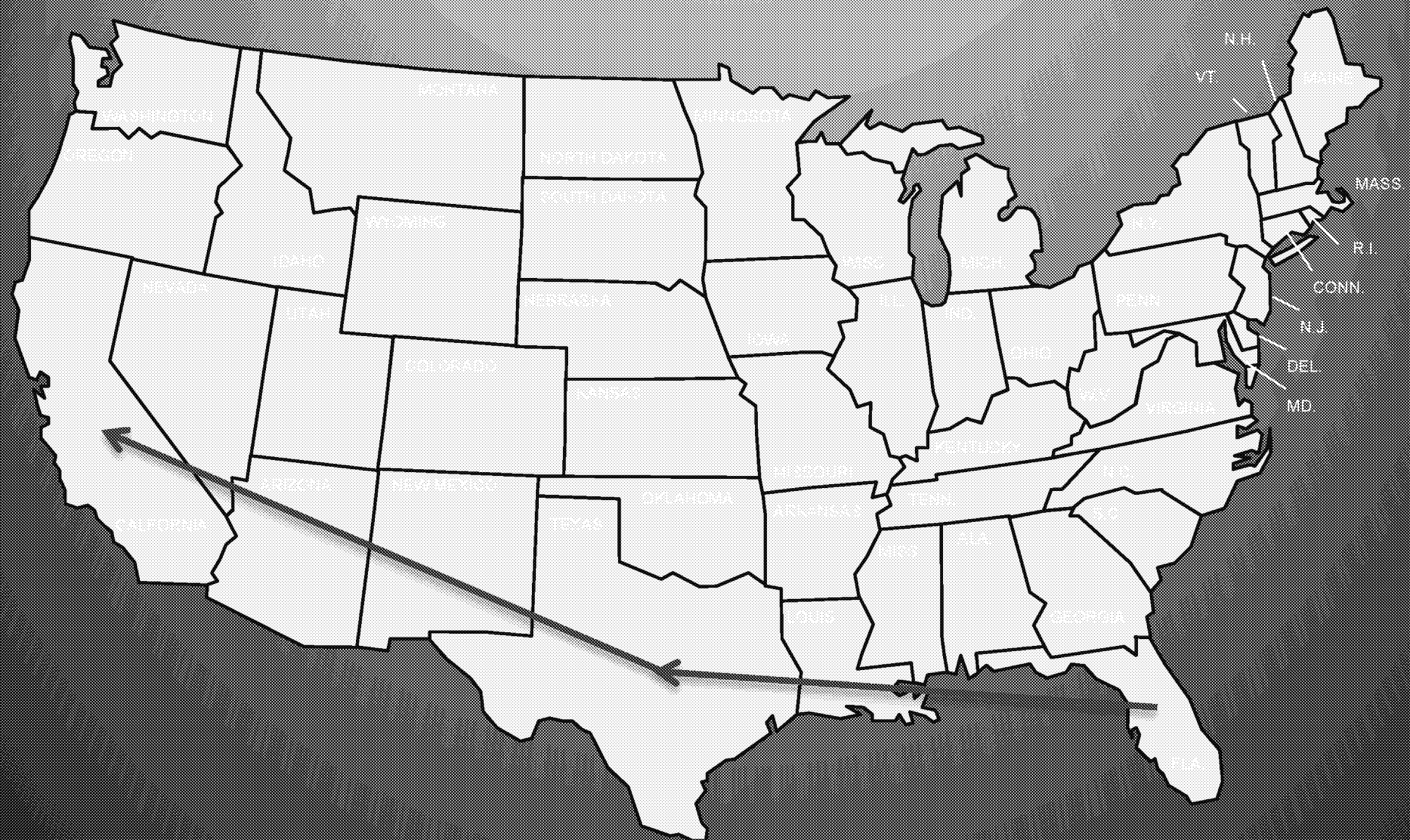
MIGRATION OF PAIN CLINICS



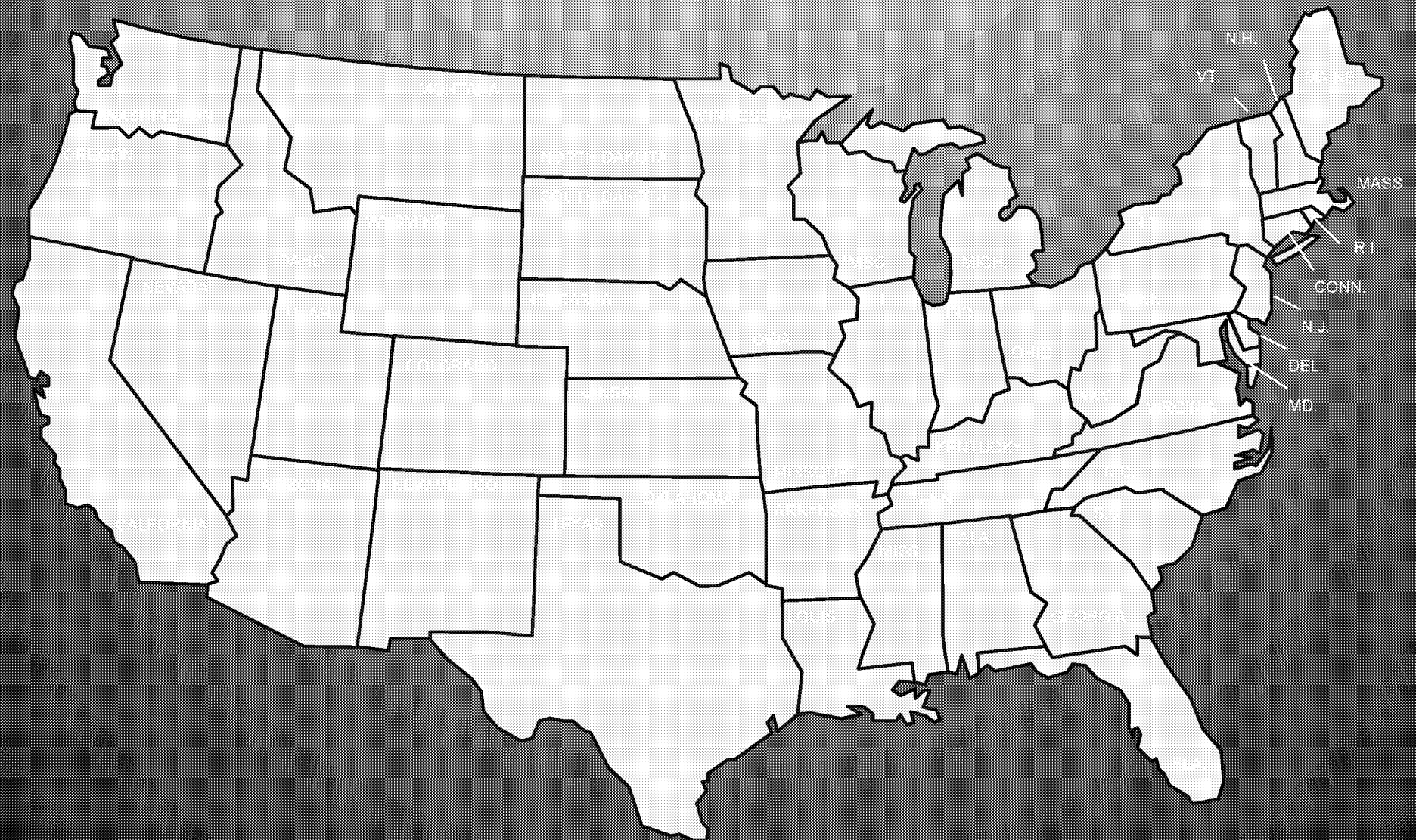
MIGRATION OF PAIN CLINICS



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